

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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TORONTO, Ontario
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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing 30 June 2006 (30-06-2006)
(day/month/year)

Applicant's or agent's file reference
307105P

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/CA2006/000320

International filing date (day/month/year)
07 March 2006 (07-03-2006)

Priority date (day/month/year)
07 March 2005 (07-03-2005)

International Patent Classification (IPC) or both national classification and IPC
IPC: *A01N 25/16* (2006.01), *C11D 17/00* (2006.01), *C11D 3/48* (2006.01), *A01N 55/10* (2006.01),
A01N 31/02 (2006.01)

Applicant
ETHENA HEALTHCARE INC. ET AL

1. This opinion contains indications relating to the following items :

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input checked="" type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/CA
Canadian Intellectual Property Office
Place du Portage I, C114 - 1st Floor, Box PCT
50 Victoria Street
Gatineau, Quebec K1A 0C9
Facsimile No.: 001(819)953-2476

Date of completion of this opinion
14 June 2006 (14-06-2006)

Authorized officer
Sandra Nevill (819) 934-6732

Box No. I **Basis of this opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

 ☒ the international application in the language in which it was filed

 ☐ a translation of the international application into _____, which is the language of a
 translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of :
 - a. type of material
 ☐ a sequence listing
 ☐ table(s) related to the sequence listing
 - b. format of material
 ☐ on paper
 ☐ in electronic form
 - c. time of filing/furnishing
 ☐ contained in the international application as filed.
 ☐ filed together with the international application in electronic form
 ☐ furnished subsequently to this Authority for the purposes of search.
- 3 ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statement that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments :

Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	6, 7, 9, 10, 13, 16, 19-26, 29, 35-39, 41-44, 47, 48, 51, 55-58, 60, 61, 65, 67-71, 76-79, 82-87	YES
	Claims	1-5, 8, 11, 12, 14, 15, 17, 18, 27, 28, 30-34, 40, 45, 46, 49, 50, 52-54, 59, 62-64, 66, 72-75, 80, 81	NO
Inventive step (IS)	Claims	6, 7, 9, 10, 13, 16, 19-26, 29, 35-39, 41-44, 47, 48, 51, 55-58, 60, 61, 65, 67-71, 76-79, 82-87	YES
	Claims	1-5, 8, 11, 12, 14, 15, 17, 18, 27, 28, 30-34, 40, 45, 46, 49, 50, 52-54, 59, 62-64, 66, 72-75, 80, 81	NO
Industrial applicability (IA)	Claims	1-87	YES
	Claims	None	NO

2. Citations and explanations :

Reference is made to the following documents:

D1: US 5629006 (BECTON, DICKINSON AND COMPANY) 13 May 1997 (13-05-1997)
D2: CA 2534692 (LRC PRODUCTS LIMITED) 17 February 2005 (17-02-2005)

D1 discloses a skin disinfecting formulation that is formulated as a foam which comprises an alcohol (e.g. ethanol - 50 - 80%), a polyether-modified siloxane surfactant (e.g. polydimethyl siloxane-polyethyleneoxide - 0.25 - 5%), optionally an additional surfactant and water.

D2 discloses a foamable parasitocidal composition comprising an alcohol (e.g. ethanol - up to 60%), a silicone surfactant (up to 10%), optionally an additional surfactant and water.

Novelty (N)

Claims 1-5, 8, 11, 12, 14, 15, 17, 18, 27, 28, 30-34, 40, 45, 46, 49, 50, 52-54, 59, 62-64, 66, 72-75, 80, 81 do not comply with PCT Article 33(2). The subject matter of these claims is known as it is disclosed in D1.

D1 discloses a silicone surfactant and alcohol in a foaming composition. The silicone surfactant is polyalkylaneoxide dimethylsiloxane copolymer. The additional surfactant is a foaming surfactant e.g. cetyltrimethyl amino oxide.

Claims 1-3, 5, 11, 12, 14, 17, 18, 28, 30-34, 40 do not comply with PCT Article 33(2). The subject matter of these claims is known as it is disclosed in D2.

D2 discloses a composition for destroying parasites specifically head lice. The foaming composition comprises a silicone surfactant and alcohol with an optional additional surfactant. The only silicone surfactants disclosed are cyclomethicone and hydroxy-terminated linear siloxane. Additional surfactants have a large number of possibilities including amine oxides.

Inventive Step (IS)

Claims 6, 7, 9, 10, 13, 16, 19-26, 29, 35-39, 41-44, 47, 48, 51, 55-58, 60, 61, 65, 67-71, 76-79, 82-87 do comply with Article 33(3) of the PCT. The problem to be solved by the present application is considered to be the formulation of a foaming alcohol disinfecting composition which does not need to be removed after use with rinsing. The solution proposed by the present application is the use of bis-PEG-[10-20]-dimethicone, 3-(3-hydroxypropyl)-heptamethyltrisiloxane, ethoxylated, acetate, polysiloxane betaine and mixtures thereof as surfactants. None of the prior art suggest the use of these surfactants for this purpose. Therefore, claims 6, 7, 9, 10, 13, 16, 19-26, 29, 35-39, 41-44, 47, 48, 51, 55-58, 60, 61, 65, 67-71, 76-79, 82-87 are considered to involve an inventive step.

Industrial Applicability (IA)

The subject matter of claims 1-87 is considered to be industrially applicable and complies with the requirements of Article 33(4) of the PCT.

Box No. VII **Certain defects in the international application**

The following defects in the form or contents of the international application have been noted :

The statements as found on pages 1 and 14 , which incorporates documents by reference, do not comply with Article 5 PCT, and must be removed.

There are no periods at the end of claims 7, 8, 58, 59.

The word silicone is misspelled in claim 28.

There is a space missing between 34 and wherein in claim 36.

The word dimethyl diammonium is misspelled in claims 37 and 69.

There are two commas missing in claims 43 and 78, one between carbon dioxide and butane, and one between ethane and octafluorocyclobutane.

Claim 45 has an extra 0.01 in line 5.

Claim 65 has excess periods between cocoate and combinations and between 5% and the word and.

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made :

The application does not meet the requirements of Article 6 of the PCT for the following reasons:

Claims 1 and 45 are missing features essential to the working of the invention. Claim 1 is missing the range of the silicone-based surfactant of 0.001 - 10% as taught in the description on page 7, line 1. In claim 45, the silicone surfactant is not claimed as being physiologically acceptable, which is also essential as taught on page 6 of the description.

The use of the following terms causes a lack of clarity:

- includes (claims 1, 45, 48, 52)
- including (claims 17, 27, 30, 33, 34, 44, 45, 53, 64-66, 72, 73, 79, 80, 81)
- foamable (claims 1, 2)
- greater than about (claim 1)
- silicone imidazole/amine/alkyl quats (claims 3, 54)
- about (claims 4, 11, 18, 27, 30, 31, 33, 36-39, 42, 44, 45, 49, 51, 52, 68-74, 77, 79, 82, 85, 86)
- and/or (claims 18, 81)
- moles (claims 21-23)
- such as (claims 28, 62)
- at least from about (claim 45)
- pre-selected (claim 74)
- and the like, may be, commonly added (claim 81)

Claims 1, 45 and 52 are indefinite. The elements, R and n, are undefined.

Claims 29, 30, 63-65 do not conform to proper Markush claim structure. The use of or to separate elements causes a lack of clarity. The elements must be separated only by commas and the final element by the word and.

There is no support within the description for the subject matter of claims 31, 32, 40, 72-75, 81, 84-87.

There is no support within the description for the following elements:

- methanol (claim 5)
- alcohol range of 40-90% (claim 11)

Claim 26 has no additional features over claim 7.

Claim 73 has no additional features over claim 72.